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IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

HAILEE PAXTON, an individual; PENNY RIDLEY, an individual; DANNA SALVALEON-CUA, an individual; MELISSA SIGMON, an individual; CASEY SLONE, an individual; SHANNON SMITH, an individual; TANYA TODD, an individual; CONSTANCE EDWARDS, an individual; PARIS HOOKS, an individual; CASSIE MCGRANE, an individual; LAUREEN GREEN, an individual; TINA KING, an individual; SHERRY NELSON, an individual; HEATHER ROBY, an individual; CIARA PARNELL, an individual; DANIELLE THATE, an individual; KATHERINE ZUB, an individual; STEPHANIE SOLLIS, an individual; JENEAY JACKSON, an individual; BRITTANY MEDINGER, an individual; LYNN SCHROEDER, an individual; JORDAN SASSMAN, an individual; and AMANDA WALTON, an individual

Plaintiffs,

Case No. CV13-08104-DMG (PLAx)

COMPLAINT FOR:

(1) DEFECTIVE MANUFACTURING
(2) DESIGN DEFECT
(3) NEGLIGENCE
(4) FAILURE TO WARN
(5) STRICT LIABILITY
(6) BREACH OF IMPLIED WARRANTY
(7) BREACH OF EXPRESS WARRANTY
(8) NEGLIGENT MISREPRESENTATION
(9) FRAUDULENT MISREPRESENTATION
(10) FRAUD BY CONCEALMENT

vs.

BAYER HEALTHCARE PHARMACEUTICALS, INC., DOES 1-10.

Defendants.

JURY TRIAL DEMANDED

INTRODUCTION

Plaintiffs Hailee Paxton, Penny Ridley, Danna Salvaleon-Cua, Melissa Sigmon, Casey Slone, Shannon Smith, Tanya Todd, Constance Edwards, Paris Hooks, Cassie McGrane, Laureen Green, Tina King, Sherry Nelson, Heather Roby, Ciara Parnell, Danielle Thate, Katherine Zub, Stephanie Sollis, Jeneay Jackson, Brittany Medinger, Lynn Schroeder, Jordan Sassman, and Amanda Walton (collectively, "Plaintiffs"), by and through their undersigned attorneys, hereby bring this action against the defendant, Bayer Healthcare Pharmaceuticals, Inc. ("Bayer") for personal injuries suffered as a proximate result of Plaintiffs' use of the defective and unreasonably dangerous product Mirena® (levonorgestrel-releasing intrauterine system). At all times relevant hereto, Mirena® was manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Bayer.

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendant is incorporated and has its principal places of business in states other than the states in which the Plaintiffs reside.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to at least some of Plaintiffs' claims occurred, in part, in the Central District of California and because Defendants transact business in this district.

PARTIES AND CITIZENSHIP

1. Plaintiff Hailee Paxton is a natural person and a resident and citizen of Hanson, Kentucky.

2. Plaintiff Penny Ridley is a natural person and a resident and citizen of Portsmouth, Virginia.

3. Plaintiff Sanna Salvaleon-Cua is a natural person and a resident and citizen of Palo Alto, California.

4. Plaintiff Melissa Sigmon is a natural person and a resident and citizen of Hollywood, Florida.

5. Plaintiff Casey Slone is a natural person and a resident and citizen of Pippa Passes, Florida.

6. Plaintiff Shannon Smith is a natural person and a resident and citizen of Cleveland, Ohio.

7. Plaintiff Tanya Todd is a natural person and a resident and citizen of Willacoochee, Georgia.

8. Plaintiff Constance Edwards is a natural person and a resident and citizen of Cordelle, Georgia.

9. Plaintiff Paris Hooks is a natural person and a resident and citizen of Chicago, Illinois.

10. Plaintiff Cassie McGrane is a natural person and a resident and citizen of Alexandria, Minnesota.

11. Plaintiff Laureen Green is a natural person and a resident and citizen of Pheonix, Arizona.

12. Plaintiff Tina King is a natural person and a resident and citizen of Oklahoma City, Oklahoma.

13. Plaintiff Sherry Nelson is a natural person and a resident and citizen of St. Marys, Alaska.

14. Plaintiff Heather Roby is a natural person and a resident and citizen of Waterloo, Iowa.

15. Plaintiff Ciara Parnell is a natural person and a resident and citizen of Mt. Vernon, Washington.

16. Plaintiff Danielle Thate is a natural person and a resident and citizen of Ormsby, Minnesota.

17. Plaintiff Katherine Zub is a natural person and a resident and citizen of Levittown, New York.

18. Plaintiff Stephanie Sollis is a natural person and a resident and citizen of Pueblo, Colorado.

19. Plaintiff Jeneay Jackson is a natural person and a resident and citizen of Victorville, California.

20. Plaintiff Brittany Medinger is a natural person and a resident and citizen of Bradford, Connecticut.

21. Plaintiff Lynn Schroeder is a natural person and a resident and citizen of Palm Coast, Florida.

22. Plaintiff Jordan Sassman is a natural person and a resident and citizen of Spencer, Iowa.

23. Plaintiff Amanda Walton is a natural person and a resident and citizen of Bowman, North Dakota.

24. Defendant Bayer Healthcare Pharmaceuticals Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt Road, Wayne, New Jersey 07470. Defendant Bayer Healthcare Pharmaceuticals, Inc., can be served with process through its registered agent for service of process in California, Corporation Service Company, 2710 Gateway Oaks Dr, Suite I50N, Sacramento, California 95833.

25. Defendant Bayer Healthcare Pharmaceuticals, Inc. was formerly known as Berlex, Inc., which was formerly known as Berlex Laboratories, Inc.

26. Berlex Laboratories, Inc. and Berlex, Inc. were integrated into Bayer HealthCare AG and operate as an integrated specialty pharmaceuticals business under the new name, Defendant Bayer Healthcare Pharmaceuticals, Inc.

27. Defendant Bayer Healthcare Pharmaceuticals Inc. is the holder of the approved New Drug Application (NDA) for contraceptive device Mirena®.

28. Bayer is in the business of designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing prescription drugs and women's healthcare products, including the intrauterine contraceptive system, Mirena®.

29. Bayer does business in California through the sale of Mirena® and other prescription drugs in the state.

30. At all times relevant, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, the contraceptive device, Mirena®.

FACTS

31. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

32. Mirena® is an intrauterine system that is inserted by a healthcare provider during an office visit. Mirena® is aT-shaped polyethylene frame with a steroid reservoir that releases 20 µg/day of levonorgestrel, a prescription medication used as contraceptive.

32. The federal Food and Drug Administration (FDA) approved Defendants' New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.

33. The system releases levonorgestrel, a synthetic progestrogen, directly into the uterus for birth control. Defendants admit it is not known exactly how Mirena works," but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

34. The Mirena® intrauterine system ("IUS") is designed to be placed within seven (7) days of the first day of menstruation and is approved to remain in the uterus for up to five (5) years. If continued use is desired after five years, the old system must be discarded and a new one inserted.

35. The package labeling recommends that Mirena® be used in women who have had at least one child.

36. Mirena®' s label does not warn about spontaneous migration of the IUS, but only states that migration may occur if the uterus is perforated during insertion of the device.

37. Mirena®'s label also describes perforation as an "uncommon" event, despite the numerous women who have suffered migration and perforation post insertion, clearly demonstrating this assertion to be false.

38. Defendant has a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

39. In or around December 2009, Defendant was contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications (DDMAC) regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private by a representative from “Mom Central”, a social networking internet site, and Ms. Barb Dehn, a nurse practitioner with Defendants.

40. This Simple Style program represented that Mirena® use would increase the level of intimacy, romance and emotional satisfaction between sexual

partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena®' s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

41. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

42. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage if a woman becomes pregnant on Mirena®.

43. Finally, Defendant falsely claimed that Defendant's product required no compliance with a monthly routine.

PLAINTIFF SPECIFIC FACTS

Plaintiff Hailee Paxton

44. Plaintiff Hailee Paxton had her physician in Hobkinsville, KY insert the Mirena® IUS on or about February 17, 2004.

45. As a result of Plaintiff Hailee Paxton's use of Mirena® IUS she suffered migration of the IUS that resulted in perforation of her uterus. On or about November 16, 2009, Plaintiff Hailee Paxton's Mirena® IUS was surgically removed due to the migration and because the Mirena® had perforated her uterus. Plaintiff Hailee Paxton continues to suffer from pain and discomfort as a result.

Plaintiff Penny Ridley

46. Plaintiff Penny Ridley had her physician in Norfold, VA insert the Mirena® IUS on or about December 17, 2009.

47. As a result of Plaintiff Penny Ridley's use of Mirena® IUS she suffered

migration of the IUS that resulted in perforation of her uterine lining. On or about December 2010, Plaintiff Penny Ridley's Mirena® IUS was surgically removed due to the migration and because the Mirena® had perforated her uterine lining. Plaintiff Penny Ridley continues to suffer from pain and discomfort as a result.

Plaintiff Danna Salvaleon-Cua

48. Plaintiff Danna Salvaleon-Cua had her physician in Palo Alto, CA insert the Mirena® IUS on or about December 30, 2009.

49. As a result of Plaintiff Danna Salvaleon-Cua's use of Mirena® IUS she suffered migration of the IUS which caused perforation end embedment of the IUS in her uterus. On or about May 18, 2010, Plaintiff Danna Salvaleon-Cua's Mirena® IUS was surgically removed due to the migration and because the Mirena® had perforated and embedded into her uterus. Plaintiff Danna Salvaleon-Cua continues to suffer from pain and discomfort as a result.

Plaintiff Melissa Sigmon

50. Plaintiff Melissa Sigmon had her physician in Cedar City, UT insert the Mirena® IUS on or about November 7, 2006.

51. As a result of Plaintiff Melissa Sigmon's use of the Mirena® IUS she suffered migration of the IUS which caused the string of the IUS to become coiled in her endocervical canal. On or about August 1, 2008, Plaintiff Melissa Sigmon's Mirena® IUS was surgically removed due to the migration and because the strings of the Mirena® had coiled in her endocervical canal. Plaintiff Melissa Sigmon continues to suffer from pain and discomfort as a result.

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Plaintiff Casey Slone

52. Plaintiff Casey Slone had her physician in Whiteburg, KY insert the Mirena® IUS on or about April 2, 2010.

53. As a result of Plaintiff Casey Slone's use of the Mirena® IUS she suffered migration of the IUS that resulted in embedment and perforation of the IUS in her uterus. On or about May 27, 2010, Plaintiff Casey Slone's Mirena® IUS was surgically removed due to migration and because the Mirena® had embedded into her uterine wall and perforated through her uterus. Plaintiff Casey Slone continues to suffer from pain and discomfort as a result.

Plaintiff Shannon Smith

54. Plaintiff Shannon Smith had her physician in Bedford, OH insert the Mirena® IUS on or about January 2, 2009.

55. As a result of Plaintiff Shannon Smith's use of Mirena® IUS she suffered migration of the IUS that resulted in embedment and perforation of the IUS in her uterus. On or about 2009, Plaintiff Shannon Smith's Mirena® IUS was surgically removed due to migration of the IUS and embedment and perforation of the Mirena® in her uterus. Plaintiff Shannon Smith continues to suffer from pain and discomfort.

Plaintiff Tanya Todd

56. Plaintiff Tanya Todd had her physician in Marietta, GA insert the IUS on or about 2007.

57. As a result of Plaintiff Tanya Todd's use of Mirena® IUS she suffered migration of the IUS that resulted in embedment of the IUS in her uterus. On or about March 20, 2010, Plaintiff Tanya Todd's Mirena® IUS was surgically removed due to migration of the IUS and embedment of the Mirena® in her uterus. Plaintiff Tanya Todd continues to suffer from pain and discomfort.

Plaintiff Constance Edwards

58. Plaintiff Constance Edwards had her physician in Americus, GA insert the Mirena® IUS on or about September 8, 2006.

59. As a result of Plaintiff Constance Edwards's use of the Mirena® IUS she suffered migration that resulted in embedment of the IUS in her uterine wall. On or about July 7, 2008, Plaintiff Constance Edwards's Mirena® IUS was surgically removed due to migration and embedment of the Mirena® IUS in her uterine wall. Plaintiff Constance Edwards continues to suffer from pain and discomfort as a result.

Plaintiff Paris Hooks

60. Plaintiff Paris Hooks had her physician in Chicago, IL insert the Mirena® IUS on or about April 29, 2009.

61. As a result of Plaintiff Paris Hooks' use of the Mirena® IUS she suffered migration of the IUS which caused embedment and perforation of the IUS in her uterine wall. On or about June 6, 2013, Plaintiff Paris Hooks' Mirena® IUS was surgically removed due to migration, embedment, and perforation of the Mirena® in her uterine wall. In addition, as a result of the migration, embedment, and perforation of the IUS in Plaintiff Paris Hooks' uterus, she also had to have a right oophorectomy (removal of her right ovary). Plaintiff Paris Hooks continues to suffer from pain and discomfort as a result.

Plaintiff Cassie McGrane

62. Plaintiff Cassie McGrane had her physician in Alexandria, MN insert the Mirena® IUS on or about March 6, 2006.

63. As a result of Plaintiff Cassie McGrane's use of the Mirena® IUS she suffered migration of the IUS to the left side of her pelvis that resulted in perforation of her uterus. On or about March 16, 2006, Plaintiff Cassie McGrane's Mirena® IUS

was surgically removed due to the migration and because the Mirena® had perforated her uterus. Plaintiff Cassie McGrane continues to suffer from pain and discomfort as a result.

Plaintiff Laureen Green

64. Plaintiff Laureen Green had her physician in Phoenix, AZ insert the Mirena® IUS on or about March 8, 2006.

65. As a result of Plaintiff Laureen Green's use of the Mirena® IUS she suffered migration of the IUS to her abdominal cavity and embedment and perforation of the IUS in her uterus. On or about May 14, 2008, Plaintiff Laureen Green's Mirena® IUS was surgically removed due to the migration and because the Mirena® had perforated her uterus. Plaintiff Laureen Green continues to suffer from pain and discomfort as a result.

Plaintiff Tina King

66. Plaintiff Tina King had her physician in Oklahoma City, OK insert the Mirena® IUS on or about September 14, 2011.

67. As a result of Plaintiff Tina King's use of the Mirena® IUS she suffered migration of the IUS to her pelvis that resulted in embedment of the IUS in her uterine lining. On or about November 14, 2011, Plaintiff Tina King's Mirena® IUS was surgically removed due to the migration and because the Mirena® had embedded into her uterine lining. Plaintiff Tina King continues to suffer from pain and discomfort as a result.

Plaintiff Sherry Nelson

68. Plaintiff Sherry Nelson had her physician in Bethel, AK insert the Mirena® IUS on or about November 12, 2010.

69. As a result of Plaintiff Sherry Nelson's use of the Mirena® IUS she

suffered migration of the IUS to her mid pelvic area and embedment of the IUS in her uterine lining. On or about November 16, 2010, Plaintiff Sherry Nelson's Mirena® IUS was surgically removed due to the migration and because the Mirena® had embedded into her uterine lining. Plaintiff Sherry Nelson continues to suffer from pain and discomfort as a result.

Plaintiff Heather Roby

70. Plaintiff Heather Roby had her physician in Iowa insert the Mirena® IUS on or about November 2011.

71. As a result of Plaintiff Heather Roby's use of the Mirena® IUS she suffered migration of the IUS to her endometrial cavity that resulted in embedment and perforation of the IUS in her uterus. On or about December 5, 2011 Plaintiff Heather Roby's Mirena® IUS was surgically removed due to the migration and because the Mirena® had embedded into and perforated her uterus. Plaintiff Heather Roby continues to suffer from pain and discomfort as a result.

Plaintiff Ciara Parnell

72. Plaintiff Ciara Parnell had her physician in Bellingham, WA insert the Mirena® IUS on or about December 13, 2007.

73. As a result of Plaintiff Ciara Parnell's use of the Mirena® IUS she suffered migration of the IUS that resulted in embedment and perforation of the IUS in her uterine lining. On or about April 11, 2011 Plaintiff Ciara Parnell's Mirena® IUS was surgically removed due to the migration and because the Mirena® had embedded into her uterine lining. Plaintiff Ciara Parnell continues to suffer from pain and discomfort as a result.

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Plaintiff Danielle Thate

74. Plaintiff Danielle Thate had her physician in Minnesota insert the Mirena® IUS on or about 2008.

75. As a result of Plaintiff Danielle Thate's use of the Mirena® IUS she suffered migration of the IUS to her abdominal cavity which resulted in further injuries. On or about 2010 Plaintiff Danielle Thate's Mirena® IUS was surgically removed due to the migration. Plaintiff Danielle Thate continues to suffer from pain and discomfort as a result.

Plaintiff Katherine Zub

76. Plaintiff Katherine Zub had her physician in Garden City, NY insert the Mirena® IUS on or about January 12, 2007.

77. As a result of Plaintiff Katherine Zub's use of the Mirena® IUS she suffered migration of the IUS causing the string of the IUS to become coiled insider her cervix. On or about February 16, 2012 Plaintiff Katherine Zub's Mirena® IUS was surgically removed due to the migration and because the strings of the Mirena® had coiled insider her cervix. Plaintiff Katherine Zub continues to suffer from pain and discomfort as a result.

Plaintiff Stephanie Sollis

78. Plaintiff Stephanie Sollis had her physician in Colorado insert the Mirena® IUS on or about August 2008.

79. As a result of Plaintiff Stephanie Sollis' use of Mirena® IUS she suffered migration of the IUS that resulted in perforation of her uterus. On or about November 2011, Plaintiff Stephanie Sollis' Mirena® IUS was surgically removed due to the migration and perforation of the Mirena® IUS in her uterus. Plaintiff Stephanie Sollis continues to suffer from pain and discomfort as a result.

Plaintiff Jeneay Jackson

80. Plaintiff Jeneay Jackson had her physician in Victorville, CA insert the Mirena® IUS on or about March 31, 2011.

81. As a result of Plaintiff Jeneay Jackson's use of Mirena® IUS she suffered migration of the IUS that resulted in perforation of her uterine lining. On or about June 8, 2012, Plaintiff Jeneay Jackson's Mirena® IUS was surgically removed due to the migration and because the Mirena® had perforated her uterine lining. Plaintiff Jeneay Jackson continues to suffer from pain and discomfort as a result.

Plaintiff Brittany Medinger

82. Plaintiff Brittnay Medinger had her physician in Bradford, CT insert the Mirena® IUS on or about 2010.

83. As a result of Plaintiff Brittany Medinger's use of Mirena® IUS she suffered migration of the device that resulted in embedment of the IUS. On or about June 30, 2011, Plaintiff Brittany Medinger's Mirena® IUS was surgically removed due to the migration and embedment of the Mirena®. Plaintiff Brittany Medinger continues to suffer from pain and discomfort as a result.

Plaintiff Lynn Schroeder

84. Plaintiff Lynn Schroeder had her physician in St. Augustine, FL insert the Mirena® IUS on or about May 11, 2006.

85. As a result of Plaintiff Lynn Schroeder's use of Mirena® IUS she suffered migration of the IUS to her abdominal cavity that resulted in injuries. On or about October 19, 2010, Plaintiff Lynn Schroeder's Mirena® IUS was surgically removed due to the migration of the Mirena®. Plaintiff Lynn Schroeder continues to suffer from pain and discomfort as a result.

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Plaintiff Jordan Sassman

86. Plaintiff Jordan Sassman had her physician in Desmoinen, IA insert the Mirena® IUS on or about July 1, 2010.

87. As a result of Plaintiff Jordan Sassman's use of Mirena® IUS she suffered migration of the device that resulted in embedment of the IUS. On or about February 7, 2013, Plaintiff Jordan Sassman's Mirena® IUS was surgically removed due to the migration and embedment of the Mirena®. Plaintiff Jordan Sassman continues to suffer from pain and discomfort as a result.

Plaintiff Amanda Walton

88. Plaintiff Amanda Walton had her physician in Alamogordo, NM insert the Mirena® IUS on or about July 26, 2007.

89. As a result of Plaintiff Amanda Walton's use of the Mirena® IUS she suffered migration of the IUS that caused the string of the IUS to become coiled into her endometrial cavity. On or about October 26, 2011, Plaintiff Amanda Walton's Mirena® IUS was surgically removed due to the migration and because the strings of the Mirena® had coiled in her endometrial cavity. Plaintiff Amanda Walton continues to suffer from pain and discomfort as a result.

FIRST CAUSE OF ACTION:
DEFECTIVE MANUFACTURING

90. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

91. Defendant was and is engaged in the business of selling Mirena® in the State of California.

92. The Mirena® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised,

distributed and sold by Defendant was expected to, and did, reach each of the Plaintiffs without substantial change in the condition in which it was sold.

93. Defendants have introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of Mirena® outweighs any benefit derived therefrom. The unreasonably dangerous nature of Mirena® caused serious harm to Plaintiffs.

94. Defendants manufactured, marketed, promoted and sold a product that was not merchantable and/or reasonably suited to the use intended, and its condition when sold was the proximate cause of the injuries sustained by the Plaintiffs.

95. As a direct and proximate result of Plaintiffs' use of Mirena®, they were each forced to undergo surgical removal of the IUS, developed severe pain from the device and had to undergo numerous procedures.

96. Defendant placed Mirena® into the stream commerce wanton reckless disregard for the public safety.

97. Defendant knew and, in fact, advertised and promoted the use of Mirena® despite their failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of the Defendant's advertising and widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

98. Despite the fact that evidence existed that the use of Mirena® was dangerous and likely to place users at serious risk to their health, Defendant failed to disclose and warn of the health hazards and risks associated with the Mirena® and in fact acted to deceive the medical community and public at large, including all potential users of Mirena® by promoting it as safe and effective.

99. Defendant knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

100. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

101. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries, required medical treatment, and incurred and continue to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SECOND CAUSE OF ACTION:

DESIGN DEFECT

102. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

103. Defendants were and are engaged in the business of selling Mirena® the State of California.

104. The Mirena® manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendant was expected to, and did, reach Plaintiffs without substantial change in the condition in which it was sold.

105. The foreseeable risks associated with the design or formulation of the Mirena® include, but are not limited to, the fact that the design or formulation of Mirena® is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

106. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, istributed and sold a product that was not merchantable and/or reasonably suited to

the use intended, and its condition when sold was the proximate cause of the injuries sustained by Plaintiffs.

107. As a direct and proximate cause of Plaintiffs' use of Mirena®, she was forced to undergo surgical removal of the Mirena®, developed severe pain, and underwent numerous procedures.

108. Defendant placed Mirena® into the stream of commerce with wanton and reckless disregard for the public safety.

109. Defendant knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

110. There are contraceptives on the market with safer alternative designs that they provide equal or greater efficacy and far less risk.

111. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries, required medical treatment, and incurred and continue to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

THIRD CAUSE OF ACTION:

NEGLIGENCE

112. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

113. Upon information and belief, Defendant failed to use reasonable care in designing Mirena® in that they:

a. failed to properly and thoroughly test Mirena® before releasing the drug to market;

b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Mirena®;

c. failed to conduct sufficient post-market testing and surveillance of Mirena®;

d. designed, manufactured, marketed, advertised, distributed, and sold Mirena® to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of Mirena® and without proper instructions to avoid the harm which could foreseeable occur as a result of using the drug

e. failed to exercise due care when adve1 1ising and promoting Mirena®; and

f. negligently continued to manufacture, market, advertise, and distribute Mirena® after Defendants knew or should have known of its adverse effects.

114. A reasonable manufacturer would or should have known that its risks created by Mirena® are unreasonably greater than that of other contraceptives and that Mirena® has no clinical benefit over such other contraceptives that compensates in whole or part for the increased risk.

115. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries, required medical treatment, and incurred and continue to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FOURTH CAUSE OF ACTION:

FAILURE TO WARN

116. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

117. Mirena® is a defective and therefore an unreasonably dangerous product, because its labeling fails to adequately warn consumers and prescribers of, among other things, the risk of migration of the product post-insertion, uterine perforation post-insertion, or the possibility that device complications such as migration and perforation may cause abscesses, infections require surgery for removal and/or may necessitate hysterectomy, oophorectomy, and other complications.

118. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold and otherwise released into the stream of commerce the pharmaceutical, Mirena®, and in the course of same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Mirena®.

119. Mirena® was under the exclusive control of Defendant and was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendant further diluted or minimized the warnings given with the product.

120. Defendant downplayed the serious and dangerous side effects of Mirena® to encourage sales of the product; consequently, Defendant placed its profits above its customers' safety.

121. Mirena® was defective and unreasonably dangerous when it left the possession of Defendant in that it contained warnings insufficient to alert Plaintiffs

to the dangerous risks and reactions associated with it. Even though Defendants knew or should have known of the risks associated with Mirena®, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product.

122. Plaintiffs used Mirena® as intended and as indicated by the package labeling or in a reasonably foreseeable manner.

123. Plaintiffs could not have discovered any defect in Mirena® through the exercise of reasonable care.

124. Defendant, as manufactures of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendant had knowledge of the dangerous risk and side effects of Mirena®.

125. Plaintiffs did not have the same knowledge as Defendant and no adequate warning was communicated to her physician(s).

126. Defendant had a continuing duty to warn consumers, including Plaintiffs and each of their physicians, and the medical community of the dangers associated with Mirena®, and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendant breached their duty.

127. Although Defendant knew, or were reckless in not knowing, of the defective nature of Mirena®, they continued to manufacture, design, formulate, test, package, label, produce, create, made, construct, assemble, market, advertise, distribute and sell Mirena® without providing adequate warnings and instructions concerning the use of Mirena® so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by Mirena®.

128. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries, required medical treatment, and incurred and continue to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

FIFTH CAUSE OF ACTION:
STRICT LIABILITY

129. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

130. Defendant is a manufacturer and/or supplier of Mirena® and are strictly liable to Plaintiffs for manufacturing, designing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, marketing, advertising, distributing, selling and placing Mirena® into the stream of commerce.

131. Mirena®, manufactured and/or supplied by Defendant, was defective in design or formulation in that when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous. It was more dangerous than an ordinary consumer would expect and more dangerous than other contraceptives.

132. Mirena® was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

133. Mirena® was also defective due to inadequate warnings or instructions because the manufacturer knew or should have known that Mirena® created, among other things, a risk of perforation and migration and associated infections or conditions and the Defendants failed to adequately warn of these risks.

134. Mirena® was defective due to inadequate pre-marketing testing.

135. Defendant failed to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or

should have known of the extreme risks associated with Mirena® and continue to promote Mirena® in the absence of those adequate warnings.

136. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries, required medical treatment, and incurred and continue to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all suck other relief as the Court deems appropriate pursuant to the common law and statutory law.

SIXTH CAUSE OF ACTION:
BREACH OF IMPLIED WARRANTY

137. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

138. Defendant manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® as safe for use by the public at large, including Plaintiff, who purchased Mirena®. Defendants knew the use for which their product was intended and impliedly warranted the product to be of merchantable quality, safe and fit for use.

139. Plaintiffs reasonably relied on the skill and judgment of the Defendant, and as such their implied warranty, in using Mirena®.

140. Contrary to same, Mirena® was not of merchantable quality or safe or for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used.

141. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries, required medical treatment, and incurred and continue to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

SEVENTH CAUSE OF ACTION:

BREACH OF EXPRESS WARRANTY

142. Plaintiffs incorporate by reference all other paragraphs complaint as if fully set forth herein, and further allege as follows:

143. The aforementioned designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® were expressly warranted to be safe by Defendant for Plaintiffs and members of the public generally. At the time of the making of these express warranties, Defendant had knowledge of the foreseeable purposes for which Mirena® was to be used and Defendant warranted Mirena® to be in all respects safe, effective and proper for such purposes.

144. Mirena® does not conform to these express warranties and representations because Mirena® is not safe or effective and may produce serious side effects.

145. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries, required medical treatment and incurred medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

EIGHTH CAUSE OF ACTION:

NEGLIGENT MISREPRESENTATION

146. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

147. Defendant, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena®, owed a duty to provide accurate and complete information regarding Mirena®.

148. Defendant falsely represented to Plaintiffs that Mirena® was a safe and effective contraceptive option. The representations by Defendant were in fact false, as Mirena® is not safe and is dangerous to the health of its users.

149. At the time the aforesaid representations were made, Defendant concealed from Plaintiffs and their health care providers, information about the propensity of Mirena® to cause great harm. Defendant negligently misrepresented claims regarding the safety and efficacy of Mirena® despite the lack of information regarding same.

150. These misrepresentations were made by Defendant with the intent to induce Plaintiffs to use Mirena®, which caused each of their injuries.

151. At the time of Defendant's misrepresentations and omissions, Plaintiffs were ignorant of the falsity of these statements and reasonably believed them to be true.

152. Defendant breached their duties to Plaintiffs by providing false, incomplete and/or misleading information regarding their product. Plaintiffs reasonably believed Defendant's representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Mirena®.

153. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs suffered profound injuries, required medical treatment, and incurred and continue to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

NINTH CAUSE OF ACTION:
FRAUDULENT MISREPRESENTATION

154. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

155. Defendant, having undertaken the designing, manufacturing, marketing, formulating, testing, packaging, labeling, producing, creating, making, constructing, assembling, advertising, and distributing of Mirena® described herein, owed a duty to provide accurate and complete information regarding Mirena®.

156. Defendant fraudulently misrepresented material facts and information regarding Mirena® including, but not limited to, its propensity to cause serious physical harm.

157. At the time of Defendant's fraudulent misrepresentations and omissions, Plaintiffs were unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

158. Defendant knew this information to be false, incomplete and misleading.

159. Defendant intended to deceive and mislead Plaintiffs so that they might rely on these fraudulent misrepresentations.

160. Plaintiffs had a right to rely on and did reasonably rely upon Defendant's deceptive, inaccurate and fraudulent misrepresentations.

161. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiff s profound injuries, required medical treatment, and incurred and continue to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

TENTH CAUSE OF ACTION:

FRAUD BY CONCEALMENT

162. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

163. Defendant had a duty and obligation to disclose to Plaintiffs that Mirena® was dangerous and likely to cause serious health consequences to users when used as prescribed.

164. Defendant intentionally, willfully, and maliciously concealed and/or suppressed the facts set forth above from Plaintiffs with the intent to defraud her as herein alleged.

165. Neither Plaintiffs nor any of their physicians were aware of the facts set forth above, and had they been aware of said facts would not have prescribed this product.

166. As a proximate result of the concealment and/or suppression of the facts set forth above, Plaintiffs have proximately sustained damage, as set forth herein.

167. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendant, Plaintiffs have suffered profound injuries, required medical treatment, and incurred and continue to incur medical and hospital expenses.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

REQUEST FOR PUNITIVE DAMAGES

168. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

169. At all times relevant herein, Defendant:

a. knew that Mirena® was dangerous and ineffective;

b. concealed the dangers and health risks from Plaintiffs, physicians, pharmacists, other medical providers, the FDA, and the public at large;

c. made misrepresentations to Plaintiffs, her physicians, pharmacists, hospitals and medical providers and the public in general as previously stated herein as to the safety and efficacy of Mirena®; and

d. with full knowledge the health risks associated with Mirena® and without adequate warnings of the same, manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed and sold Mirena® for routine use.

170. Defendant, by and through officers, directors, managing agents, authorized sales representatives, employees and/or other agents who engaged in malicious, fraudulent and oppressive conduct towards Plaintiffs and the public, acted with willful and wanton and/or conscious and reckless disregard for the safety of Plaintiffs and the general public.

171. As a direct and proximate result of one or more of these wrongful acts or omissions of the Defendants, Plaintiffs suffered profound injuries that required medical treatment and incurred medical and hospital expenses, for which Plaintiffs have become liable.

WHEREFORE, Plaintiffs demand judgment against Defendant for compensatory, statutory and punitive damages, together with interest, costs of suit,

attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

PRAYER FOR RELIEF

Plaintiffs demand judgment against Defendant for compensatory, and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

DATED: October 31, 2013

KABATECK BROWN KELLNER LLP

By _____
Lina B. Melidonian
Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury on all Counts and as to all issues.

Respectfully submitted,

DATED: October 31, 2013

KABATECK BROWN KELLNER LLP

By _____
Lina B. Melidonian
Attorneys for Plaintiffs